# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE COMPANY and HOFFMANN-LA ROCHE INC.,	
Plaintiffs, )	C.A. No. 08-627-JJF
v. )	
TEVA PHARMACEUTICALS USA, INC.,	
Defendant.	
THE PROCTER & GAMBLE COMPANY and HOFFMANN-LA ROCHE INC.,	; ;
Plaintiffs, )	, ,
v. )	C.A. No. 09-143-JJF (consolidated with C.A. No. 08-627-JJF for pretrial purposes)
APOTEX, INC. AND APOTEX CORP.,	ior promise pusposos)
Defendants. )	
,	

DEFENDANTS' APOTEX INC.'S AND APOTEX CORP.'S MOTION TO EXTEND DEADLINES FOR FACT DISCOVERY, EXPERT REPORTS, AND TO ENTER A BRIEFING SCHEDULE FOR CLAIM CONSTRUCTION BRIEFS

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Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") request the Court to enter an Order to extend the close of fact discovery until forty-five (45) days after the Court's Markman decision and to extend expert deadlines so that reports from retained experts required by Fed. R. Civ. P. 26(a)(2) are due from the party with the burden of proof on the issue the expert is offered seventy-five (75) days after the Court's Markman decision. Apotex further requests the Court to extend the date suggested for a Markman Hearing until December 9, 2010 and to enter a briefing schedule for claim construction briefs. Despite the upcoming July 7, 2010 deadline, Plaintiffs have not yet completed document production and have not provided substantive responses to Defendants' interrogatories. Plaintiffs have not provided a date certain for completion of document production or supplemental interrogatory responses and Apotex has filed Defendants' Apotex Inc,'s and Apotex Corp,'s Motion to Compel to Compel Discovery ("Motion to Compel") these responses. Regardless of whether Plaintiffs supplement interrogatory responses and complete document production by the July 7, 2010 deadline, these deadline extensions are necessary to permit Apotex to conduct further discovery based on the responses and documents provided by Plaintiffs including potential third-party discovery. See, e.g., Payne v. Exxon Corp., 121 F.3d 503, 508 (9th Cir. 1997) (stating when "[m]any of the discovery responses eventually tendered by the plaintiffs came only as the discovery period was drawing to a close, or after it had already closed, [the defendants] were therefore deprived of any meaningful opportunity to follow up on that information, or to incorporate it into their litigation strategy."). Additionally, Plaintiff The Procter & Gamble Company ("P&G") filed *Plaintiffs*' Motion to Substitute Parties Pursuant to FED.R.CIV.P. 25(c) and Seeking Leave to File

<sup>&</sup>lt;sup>1</sup> Defendants Apotex Inc.'s and Apotex Corp.'s Motion to Compel Discovery was filed contemporaneously herewith.

Amended Complaints Pursuant to FED.R.CIV.P. 15(a)(2)<sup>2</sup> ("Motion to Substitute Parties") (D.I. 69) to substitute Warner Chilcott Company LLC for Plaintiff P&G. As described in further detail below Plaintiffs have not yet produced discovery relevant to this request and these extensions will permit Apotex to conduct any further discovery of the additional party.

Counsel for Apotex conferred with Plaintiffs' counsel regarding the extending deadlines. Pursuant to L.R. 7.1.1, Apotex's counsel has made a reasonable effort to reach an agreement with the opposing party on these matters. Plaintiffs would not agree to extend the fact discovery deadline. Pursuant to Local Rule 16.4 counsel has provided a copy of this request to their client.

#### I. PROCEDURAL BACKGROUND

Plaintiffs The Procter & Gamble Company and Hoffmann-La Roche Inc. (collectively "Plaintiffs") brought this lawsuit under the Hatch-Waxman Act alleging Apotex infringes one of their patents under 35 U.S.C. §271(e)(2) by submitting an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") (Civil Action No. 09-143-JJF) on March 4, 2009. On June 19, 2009 this case was consolidated with the litigation styled *The Procter & Gamble Company and Hoffmann-La Roche Inc. v. Teva Pharmaceuticals USA, Inc.* (Civil Action No. 08-627-JJF).

On June 11, 2010, the Court has entered an Amended Consolidated Rule 16 Scheduling Order (D.I. 68). Currently, the parties are to have exchanged responses to contention interrogatories, identified fact witnesses, and completed document production by July 7, 2010. (D.I. 68). The opening expert reports from the party with the burden of proof on the issue is currently ordered to be submitted by the later of thirty days after the Court's Markman decision

<sup>&</sup>lt;sup>2</sup> Apotex does not object to P&G adding Warner Chilcott Company LLC to the litigation but does object to the substitution of the parties.

or December 14, 2010 and the parties suggested the Markman hearing be on or about October 18, 2010. (D.I. 68)

On November 5, 2009, Apotex served Defendants' First Set of Requests for the Production of Documents to Plaintiff The Procter & Gamble Company (Nos. 1-61) (D.I. 38) and Defendants' First Set of Requests for the Production of Documents to Plaintiff Hoffmann-La Roche Inc. (Nos. 1-79) (D.I. 39). On November 25, 2009, Apotex served Defendants' Second Requests for the Production of Documents to Plaintiff The Procter & Gamble Company (Nos. 62-91) (D.I. 40).

Plaintiff Hoffmann-La Roche Inc. served objections to Apotex's requests on December 7, 2009 but have yet to produce any documents (D.I. 42). On January 11, 2010 Apotex received objections to its document requests directed to Plaintiff P&G from non-party Warner Chilcott Company LLC but did not receive any documents. (D.I. 45-46).

On February 26, 2010, Apotex served Defendants Apotex Inc. 's and Apotex Corp.'s First Set of Interrogatories to Plaintiffs, Defendants Apotex Inc.'s and Apotex Corp.'s Third Set of Requests for the Production of Documents and Things to Plaintiff The Procter & Gamble Company (Nos. 92-99) and Defendant Apotex Inc.'s and Apotex Corp.'s Second Set of Request for the Production of Documents and Things to Plaintiff Hoffmann-La Roche Inc. (Nos. 80-85).

(D.I. 55). On April 12, 2010, Plaintiffs had still not produced any documents but served objections to Apotex's additional requests. (D.I. 59, 64). Again, Plaintiff P&G did not respond to Apotex's requests but served objections lodged by non-party Warner Chilcott Company LLC. (D.I. 64). Plaintiffs also served responses to Apotex's interrogatories. (D.I. 62). Plaintiffs did not provide substantive responses but rather primarily lodged objections and relying on the

production of documents, which again had not yet been produced, pursuant to Fed.R.Civ.P. 33(d).

Plaintiff P&G began document production on May 28, 2010 and supplemented the production on June 16, 2010. However, the document production is lacking core documents and is currently the subject of Apotex's Motion to Compel. Similarly, Plaintiffs have not supplemented their responses to Interrogatories and have not provided a date certain to receive these responses. Plaintiffs' responses to interrogatories are also subject to Apotex's Motion to Compel.

Additionally, on June 14, 2010, Plaintiff P&G filed a Motion to Substitute Parties (D.I. 69). The Court has entered a briefing schedule for the motion.

#### II. ARGUMENT

#### A. EXTENSION OF DEADLINES IS NECESSARY

Despite Apotex's diligent efforts to obtain discovery from Plaintiffs, discovery is not near to being complete. Plaintiffs have not yet completed document production and have not supplemented interrogatories. The current July 7, 2010 deadline does not allow sufficient time for the Defendants to assess Plaintiffs' documents and supplemental responses and determine what additional discovery is necessary (*i.e.* follow up fact discovery, depositions, and third party discovery). Therefore, Apotex requests the Court grant an extension of time for the completion of fact discovery and enter a briefing schedule for claim construction. *See e.g. Associated Imports v. International Longshoremen's Assn.*, 1986 U.S. Dist. LEXIS 29681, 2-3 (S.D.N.Y. Feb. 4, 1986) (granting defendants' motion for an extension of discovery deadlines when it had taken considerable time to obtain certain information from plaintiff and to process that information.).

Specifically, Plaintiffs have the burden of proof on infringement contentions and have not to date provided substantive responses to infringement contention interrogatories. Additionally, while Plaintiffs have produced some documents, the production remains woefully deficient. Plaintiffs have not produced core documents with obvious relevance to this litigation such as lab notebooks, research notes, clinical testing, protocols, and results, data and memoranda underlying the development of the drug product and method that are subjects of the patents-insuit. These documents have been requested since November 2009, and Plaintiffs have delayed production. Plaintiffs have also produced a significant number of redacted documents including several documents that appear to be publicly available documents and documents that have been redacted in their entirety. There was no basis provided for the redactions. Although, P&G's counsel has indicated they will investigate the basis for the redactions we have yet to receive any such basis. Under the current deadlines, Defendants may not receive a basis for these redactions until fact discovery has ended. Under the current deadlines, Plaintiffs will be able to dump a substantial amount of documents on Defendants at the last minute and Defendants will not be permitted the chance to conduct the follow up discovery necessary for Defendants to prepare their defense.

Additionally, the requested extension is necessary to permit the parties to conduct any follow up discovery after the Court issues its Markman decision. Under the current deadlines, fact discovery ends long before the Court would issue its Markman decision. The Court's Markman decision could impact the Defendants' invalidity or non-infringement theories and may require additional discovery prior to the submission of expert reports.

# B. EXTENSION OF DEADLINES WILL PERMIT THE PARTIES TO CONDUCT NECESSARY DISCOVERY AFTER THE PENDING MOTIONS ARE DECIDED

There are currently motions pending that could affect the parties' discovery efforts including Apotex's Motion to Compel and P&G's Motion to Substitute Parties (D.I. 69). The resolution of these motions could substantially affect the parties' discovery efforts. Specifically, with respect to P&G's Motion to Substitute Parties, if Warner Chilcott is added or substituted as a Plaintiff in this litigation, Defendants will need additional time to conduct the appropriate discovery. For example, to date, P&G has also not produced documents concerning Warner Chilcott Company LLC's ("WC") purchase of P&G including documents relating to the transfer of any interest concerning either of the patents-in-suit, including assignments, licenses or grants made in connection with WC's purchase of P&G and all documents concerning any representations and/or warranties made with respect to the patents-in-suit in connection with WC's purchase of P&G.

#### C. THE MARKMAN DEADLINES SHOULD BE EXTENDED

The Markman Deadlines should be extended to permit the parties to resolve the current dispute as to proper parties and resolve the pending discovery disputes. As described above, there is a pending Motion to Substitute Parties and a pending Motion to Compel. Apotex suggests extending the proposed date for a Markman Hearing to on or about December 9, 2010. Further, the Court did not previously enter a briefing schedule. Apotex requests that the Court enter the following claim construction briefing schedule: the parties are to exchange terms or phrases in contention with proposed definitions on or before October 1, 2010, the parties are to submit opening claim construction briefs on or before October 19, 2010, the parties are to submit responsive claim construction briefs on or before November 19, 2010.

The new deadlines proposed by Apotex will permit the parties to continue their discovery efforts in a manner that will best assist preparing this case for trial. This proposed extension is necessary to give the parties time to take meaningful follow up written discovery, depositions of fact witnesses<sup>3</sup>, and third party discovery. For example, the new proposed deadlines will permit the parties to follow up on information collected from the other party after the relevant documents are produced and the interrogatory responses are supplemented. This will, in turn, permit the parties to incorporate any information learned into their litigation strategy as they prepare their claims and defenses for trial. Similarly, extending the fact discovery cutoff until after the Court issues a Markman decision will permit the parties to conduct any further investigation or supplementation necessary to conform with the Court's issued claim construction.

Additionally, Apotex has requested the Court extend the time for the submission of reports obtained from retained experts required by Fed.R.Civ.P. 26(a)(2) from thirty (30) days after the Court issues its Markman decision to seventy-five (75) days from the day the Court issues its Markman decision. This extension is necessary to permit the parties time to complete fact discovery (Apotex is proposing fact discovery close forty-five (45) days after the Court issues its Markman decision) and discuss the information with their experts.

#### CONCLUSION

For the foregoing reasons, Apotex requests the Court enter an Order to extend the close of fact discovery until forty-five (45) days after the Court issues its Markman decision and to extend expert deadlines so that reports from retained experts required by Fed. R. Civ. P. 26(a)(2)

<sup>&</sup>lt;sup>3</sup> The current Amended Consolidated Rule 16 Scheduling Order (D.I. 68) sets a deadline of July 7, 2010 for the identification of fact witnesses. Apotex is not requesting this deadline be extended since early identification of fact witnesses will assist in the parties deposition efforts.

are due from the party with the burden of proof on the issue the expert is offered seventy-five (75) days after the Court issues its Markman decision. Apotex further request the Court extend the date suggested for a Markman Hearing until December 9, 2010 and to enter a briefing schedule for claim construction briefs as follows: the parties will exchange terms or phrases in contention with proposed claim term definitions on or before October 1, 2010, submit opening claim construction briefs on or before October 19, 2010, submit responsive claim construction briefs on or before November 19, 1020.

Dated: July 1, 2010

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#### **CERTIFICATE OF SERVICE**

I, Richard W. Riley, hereby certify that on July 1, 2010, a true and correct copy of the foregoing Defendants' Apotex Inc.'s And Apotex Corp.'s Motion To Extend Deadlines For Fact Discovery, Expert Reports, And To Enter A Briefing Schedule For Claim Construction Briefs was caused to be served on the attorneys of record at the following addresses and in the manner indicated:

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